DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 19, 2015

Medos International Sarl
% Michelle Godin
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K143111
Trade/Device Name: Codman Certas Plus Programmable Valve; Codman Certas Tool Kit
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: October 28, 2014
Received: October 29, 2014

Dear Ms. Godin,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143111

Device Name
Codman Certas Plus Programmable Valve; Codman Certas Tool Kit

Indications for Use *(Describe)*
The Codman Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

The Codman Certas Tool Kit allows the noninvasive reading or adjustment of the valve setting.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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6. 510(k) Summary

I. Submitter

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Contact Person: Michelle Godin
Date of Submission**:** October 28, 2014

II. Device

Name of Device	Codman Certas Plus Programmable Valve Codman Certas Tool Kit
Common Name	Hydrocephalus Shunt
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Regulatory Class	II
Product Code	JXG

III. Predicate Device

Codman Certas Programmable Valve System and Codman Certas Therapy Management System (K112156)

IV. Device Description

The Codman Certas Plus Programmable Valve is a sterile, single use, implantable device designed for shunting cerebrospinal fluid (CSF) for the treatment of hydrocephalus.

The Codman Certas Plus Programmable Valves are pressure-regulating valves utilizing the ruby ball-in-cone principle with a pressure inducing spring design. Intraventricular pressure is maintained by the ball and cone valve seat design. As the differential pressure across the shunt increases, the ball further displaces from the cone, through which CSF flows, thereby increasing flow and re-establishing the selected pressure. The ball is manufactured of synthetic ruby, as is the matching cone. Together these components provide a precise fit for regulating the flow of CSF through the valve.

510(k) Summary (Cont)

IV. Device Description (Cont.)

The valve is available with 8 different performance settings for constant intraventricular pressure and drainage of CSF. Seven (7) of the settings provide for a change in operating pressure, with a range of 25 to 215 mmH_2O. The eighth setting provides a minimum opening pressure of '400' mmH_20, thus allowing a physician to turn the valve "virtually off" without the need to surgically remove the valve to limit flow. The pressure of the valve is set preoperatively and can be noninvasively changed post-implantation by using the Codman Certas Tool Kit, which employs magnetic force to select one of the 8 settings.

V. Indications for Use

The Indications for Use statements are identical to the predicate device.

The Codman Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

The Codman Certas Tool Kit allows the noninvasive reading or adjustment of the valve setting.

VI. Comparison to Predicate Device

Compared to the predicate device, the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit include the modifications listed in **Table 1**

Table 1. Modifications Proposed for the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit

Component	Modification	Rationale
Codman Certas Plus Programmable Valve	Changes to components contained in the Adjustable Mechanism of the programmable valve • Minor dimensional changes to the profile of the Cam of the Rotating Construct and dimensional changes to the Cam/Ball Arm Assembly • Addition of Ruby Bearing (same ruby material currently used in the predicate device, K112156) to through-hole of the Rotating Construct	Minor modifications improve the overall performance of the programmable valve without changing the fundamental scientific technology or intended use of the predicate device.

510(k) Summary (Cont)

Table 1. Modifications Proposed for the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit		
Component	**Modification**	**Rationale**
Codman Certas Tool Kit	**Locator Tool**: Includes 2 Locator Tools: The Low Profile Locator Tool which allows the clinician to get as close to the valve as possible in cases of edema and an Adjustable Height Locator Tool which allows the clinician to rotate the center ring to change the height of the locator when valve protrusion exists in a patient. In addition, the petals will be slightly wider for better grip on both tools. Minor enhancements to the tools include machined black centering lines versus pad printed black lines to improve precision for location and the addition of a v-groove to contain the 360° stop alignment pin for increased pin retention strength. **Indicator Tool**: Removed the black button and improved the pivot-bearing design to reduce toggle time to indicating a valve setting. Modified background of setting number and added a contoured handle. **Carrying Case**: Increased in size to accommodate 4 tools rather than 3 tools and added a bump feature for easier removal of the Adjustment Tool. **Accessory Tool**: X-ray Overlay Tool added to verify the valve setting on x-ray.	Modification of ergonomic and user interface; no change to fundamental scientific technology or intended use of predicate device.
Labeling	Updated IFU and product labeling for name change, clarification, and/or additional steps.	Labeling update to ensure proper use of device, no change to indications for use or intended use.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Bench testing on the proposed device, Codman Certas Plus Programmable Valve and Certas Tool Kit, included the following:

- Structural testing
- Pressure flow testing in accordance with ISO 7197:2009 *Neurosurgical Implants – Sterile, Single-Use Hydrocephalus Shunts and Components* and ASTM F647:1994 (R2006) *Standard Practice*

for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application

- MRI testing
- Indication and Adjustment testing
- Shelf Life testing including structural testing, pressure flow testing, and MRI testing.

Validation testing included:

- Pre-implantation Use - in-package indication and programming
- Post-implantation Use – indication and adjustments post-implantation using simulated skin thicknesses
- Valve patency
- Tool Kit validation
- Identifying the valve setting on x-ray with and without using the X-Ray Overlay Tool
- Manometer IFU language

Test results demonstrated that the acceptance criteria were met, therefore, the Codman Certas Plus Programmable Valve and the Codman Certas Tool Kit conform to expected device performance and intended use. Results of verification and validation testing have demonstrated that the proposed Codman Certas Plus Programmable Valve and the Codman Certas Tool Kit are substantially equivalent to the predicate Codman Certas Programmable Valve and Codman Therapy Management System, and that the modifications do not impact the safety or effectiveness of the proposed device.

Magnetic Resonance (MR) Testing

The safety test requirements of the ASTM MR standards for the proposed Certas Plus Programmable Valve have been met through testing (ASTM F2052-14 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment;* ASTM F2182-11a *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging;* ASTM F2119-07 (R2013) *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants;* ASTM F2213-06 (R2011) *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*).

The Codman Certas Plus Programmable Valve is MR-Conditional at 3.0 Tesla per the ASTM standards.

Biocompatibility Testing

The biocompatibility evaluations for the Codman Certas Plus Programmable Valve and the Codman Certas Tool Kit were conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and*

Testing May 1, 1995, and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process* as recognized by FDA.

Codman Certas Plus Programmable Valve

The Codman Certas Plus Programmable Valve is considered a permanent contact implant device. The only new component in the proposed device is the inclusion of a ruby bearing. Since the same ruby material is already included in the predicate Codman Certas Programmable Valve, additional biocompatibility testing was not required. However, as part of a cleaning validation for this component, cytotoxicity testing was completed with passing results.

Codman Certas Tool Kit

The Codman Certas Tool Kit is considered a surface device with limited contact (≤24 hours) with breached or compromised surfaces. Biocompatibility testing was completed with passing results. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- USP Limits Testing for USP <661> for Plastics, Physiochemical Testing

Animal Studies

No animal studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Clinical Studies

No clinical studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

VIII. Conclusion

Based upon the intended use, design, materials, function, comparison to currently marketed devices, and testing performed by Codman & Shurtleff, Inc., it is concluded that the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit was found to have a safety and effectiveness profile that is similar to the predicate device.